Complete Summary

GUIDELINE TITLE

Contraception and family planning. A guide to counseling and management.

BIBLIOGRAPHIC SOURCE(S)

Brigham and Women's Hospital. Contraception and family planning. A guide to counseling and management. Boston (MA): Brigham and Women's Hospital; 2005. 15 p. [6 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the FDA Web site for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA

determines pose a serious and significant public health concern. See the FDA Web site for more information.

Additional Notices

- On April 10, 2006 the U.S. Food and Drug Administration (FDA) released an update to the March 17, 2006 notice (see below) regarding mifepristone (Mifeprex) and misoprostol. See the FDA Web site for more information.
- On March 17, 2005, the U.S. Food and Drug Administration (FDA) issued a public health advisory to notify healthcare professionals of two additional deaths following medical abortion with mifepristone (Mifeprex) (see below for earlier FDA alerts). The FDA received verbal notification of the deaths in the United States from the manufacturer, Danco Laboratories. At this time FDA is investigating all circumstances associated with these cases and is not able to confirm the causes of death. However, all providers of medical abortion and their patients need to be aware of the specific circumstances and directions for use of this drug and all risks including sepsis when considering treatment. In particular, physicians and their patients should fully discuss early potential signs and symptoms that may warrant immediate medical evaluation. See the FDA Web site for more information.
- On November 4, 2005 the U.S. Food and Drug Administration (FDA) released an update to the July 20, 2005 notice (see below) regarding mifepristone (Mifeprex) and misoprostol. See the FDA Web site for more information.
- On July 20, 2005, Danco Laboratories and the FDA revised the BOXED WARNING and WARNINGS sections of the Prescribing Information, the Medication Guide and Patient Agreement to inform healthcare professionals of four cases of septic deaths in the United States, all reported from California, from September 2003 to June 2005 in women following medical abortion with mifepristone (Mifeprex) and misoprostol. The bacteria causing sepsis has been identified in two of the cases as Clostridium sordellii. The two confirmed cases of Clostridium sordellii did not have the usual signs and symptoms of an infection. All providers of medical abortion and their patients need to be aware of the risks of sepsis. See the FDA Web site for more information.
- On November 14, 2005, the U.S. Food and Drug Administration (FDA) notified healthcare professionals and patients of revisions to the label for Ortho Evra, a skin patch approved for birth control, that includes a bolded warning about higher exposure to estrogen for women using the weekly patch compared to taking a daily birth control pill containing 35 micrograms of estrogen. A woman on Ortho Evra may be exposed to approximately 60% more estrogen than if she were taking a typical 35 microgram estrogen birth control pill. Estrogen use is linked to blood clots in the legs and lungs and other clotting problems such as strokes and heart attacks. It is not known if women using Ortho Evra have a higher risk of serious side effects than women taking the typical 35 microgram estrogen pills. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Unwanted pregnancy

GUIDELINE CATEGORY

Counseling
Management
Prevention

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To review the following interventions concerning contraception and family planning:

- Hormonal contraception - including answers to frequently asked questions
- Barrier methods
- Intrauterine devices (IUDs)
- Emergency contraception
- Pregnancy termination

TARGET POPULATION

Women of reproductive age

INTERVENTIONS AND PRACTICES CONSIDERED

Counseling Women on the Use of the Following Contraceptive and Family Planning Methods, Prescribing Them Appropriately, and Monitoring Their Use:

Hormonal Contraception

1. Oral Contraceptive Pills (OCPs)
    - Desogestrel + ethinyl estradiol
    - Drospirenone + ethinyl estradiol
    - Norethindrone acetate + ethinyl estradiol
    - Norethindrone + ethinyl estradiol
    - Levonorgestrel + ethinyl estradiol
    - Norethindrone + mestranol
    - Norgestrel + ethinyl estradiol
    - Ethynodiol diacetate + ethinyl estradiol
    - Norgestimate + ethinyl estradiol
    - Norethindrone
    - Norgestrel
2. Other Hormonal Preparations
    - Depo-medroxyprogesterone acetate (Depo-Provera®)
    - Estrogen-progestin patches (Ortho-Evra®)
    - Vaginal Ring (NuvaRing®)
    - Levonorgestrel intrauterine (IU)

Barrier Contraception

1. Condom
2. Diaphragm
3. Cervical cap
4. Lea contraceptive barrier
5. Spermicidal jelly, film, foam, or suppositories
6. Female condom (Reality)

Intra-Uterine Devices (IUDs)

1. Copper T IUD (Paragard)
2. Levonorgestrel IUD (Mirena)

Surgical Methods for Contraception

1. Vasectomy
2. Tubal ligation

Emergency Contraception

1. Combined oral contraception pills (e.g., Preven™)
2. Levonorgestrel (LNG) (Plan B®)
3. Copper T IUD
4. Mifepristone

Pregnancy Termination

1. Screening of patient for sexually transmitted diseases (STDs)
2. Pre-procedure ultrasound
3. Patient assessment and referral pre-procedure counseling when necessary
4. Surgical termination methods
    - Suction curettage
    - Dilation and extraction
    - Induction of labor with misoprostol, prostaglandin gel (e.g., cervidil), or pitocin
5. Medical termination method
    - Mifepristone + misoprostol

MAJOR OUTCOMES CONSIDERED

- Effectiveness of contraception methods
- Adverse effects of contraception methods and pregnancy termination
- Patient satisfaction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The recommendations presented herein are based on a comprehensive assessment of recent literature on contraception and family planning.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Hormonal Contraception

Oral Contraceptive Pills (OCPs)

Oral contraceptive pills have been available since the 1960s. They primarily work by inhibiting luteinizing hormone (LH) and follicle-stimulating hormone (FSH) secretion, and therefore suppressing ovulation. In addition, they thicken the cervical mucous. The early preparations typically contained 50 micrograms of an estrogen, but modern preparations contain 20 to 35 micrograms and are called "low-dose" OCPs. Most preparations contain a combination of an estrogen (usually ethinyl estradiol, at a dose of 20 to 35 micrograms) and a progestin (norethindrone, norgestrel, desogestrel, or norgestimate). Progestin only pills are also available, and are useful in women who cannot take estrogen or who are lactating. Most combination oral contraceptive pills come in one-cycle packets, usually with 21 days of "active pills" and 7 days of inert pills. Preparations in which all of the active pills are the same combination of estrogen and progestin for the first 21 days are called "monophasic". Some of the preparations contain changing doses of the estrogen or the progestin component and these are called "phasic". There are no clinical advantages to using phasic preparations, and they may be more costly if no generic is available.

Please refer to the original guideline document for a table that provides brand and generic names (and their components), available dosages, generic equivalents, and the cost of brand name and generic equivalents.

Frequently Asked Questions about OCPs

QUESTION	ANSWER
How do I start a patient on OCPs?	Three ways: 1. Same day start (need back-up method for one week) 2. First day start: start on first day of period 3. Sunday start: start on first Sunday after period begins (need back-up method for one week) Notes: • Make sure patient is not pregnant before starting OCPs. In a regularly cycling woman who is a reliable historian, starting after the next period is usually sufficient. In women who have a history of irregular bleeding, or who are not good historians, a urine or serum human chorionic gonadotropin (HCG) should be checked before starting the OCP. • Recommend that the patient take OCP at the same time each day. • OCPs are slightly less effective in women who are obese, though pregnancy rate is still lower than for barrier method. To further reduce pregnancy risk, OCP containing ethinyl estradiol 35 micrograms orally (po) each day (qd).
What type of OCP should I prescribe?	Two considerations: 1. Dose: Low-dose is most commonly used for contraception (20 to 35 micrograms estrogen--usually ethinyl estradiol). Different types of progestin: Much is written about androgenicity of different types of progestin, but clinically, these differences are not significant. Older preparations contain 50 micrograms estrogen, but these are not used as a first choice for contraceptive (though they have other clinical uses). 2. Regimen: Monophasic pills contain the same amount of estrogen and progestin per pill. Phasic pills contain changing amounts of the estrogen or progestin component. There is no clear clinical advantage to the phasic pill. Progestin only pills are useful for lactating women.
Is the "continuous" method of taking OCPs safe?	OCPs can be taken continuously, with three active weeks of pills followed immediately by a new packet of pills (without the week of inert pills, and withdrawal bleed, in between). Women taking OCPs in this manner will not have a period. Since each pill contains both estrogen and a progestin, there is no risk of endometrial hyperplasia. Useful in women with menorrhagia, anemia, hyperandrogenism (e.g., polycystic ovarian disease), endometriosis, severe dysmenorrhea, menstrual migraines, and for patient convenience.

QUESTION	ANSWER
How should I monitor a patient on OCPs?	Need to check follow-up blood pressure before and after starting the pill. Annual visits are necessary to monitor blood pressure and to determine if any new contraindications to taking the pill.
What should I do if a patient complains of mid-cycle bleeding?	1. Wait 3 cycles to see if persists. 2. Consider work-up for other causes if bleeding is heavy or post-coital. 3. If persists, consider addition of estrogen midcycle--estradiol (e.g., estrace ® mg po qd for second 2 weeks of the cycle) or consider a different pill (e.g., one containing 30 to 35 micrograms of ethinyl estradiol).
Who should NOT take OCPs?	• Patients with previous history of venous thromboembolism • Patients with known Factor V Leiden mutation (risk of clot increased 30-fold) or other thrombophilia condition (e.g., prothrombin mutation, Protein C or S deficiency) • Smokers 35 years of age or older • History of breast cancer • Uncontrolled hypertension • History of stroke • History of migraine with neurologic symptoms (There is some controversy to this recommendation. This is a relative contraindication.) • Undiagnosed uterine bleeding • Liver disease
Is it acceptable to give a lactating woman OCPs?	Progesterone only pill is the preferable OCP in this group of patients. These pills have a slightly lower efficacy compared with estrogen-progestin pills. Of note, lactating women have lower fertility rate. Consequently, the progesterone only pill is usually adequate to prevent pregnancy. Combined oral contraceptive pills, or COC (estrogen-progestin containing) decrease the milk supply but are not harmful to the infant. Progestin only pills (POPs) do not decrease the milk supply and are not harmful, but are a little less effective than COC. In cases when an infant is being solely breast fed, POPs are preferred. However for women more than 6 weeks postpartum who are lactating infrequently, prescribing COCs or switching from POPs to COCs may be appropriate. In these women, whose infants have other sources of nutrition, the adequacy of the milk supply is less important, and prevention of pregnancy more important, since the risk of ovulation with infrequent lactation is higher.
Is it safe to give a perimenopausal woman OCPs?	The risk of deep vein thrombosis/venous thromboembolism (DVT/VTE) increases with increasing age, but if a woman is a non-smoker, the absolute risk is still low and acceptable. Often, OCPs are prescribed in this age group to control

QUESTION	ANSWER
	dysfunctional uterine bleeding and hot flashes. OCPs can be stopped at age 50 and symptoms reassessed.
What advice should I give women who want to become pregnant?	Women should use a barrier method for 2 cycles, so they can re-establish their menstrual periods and then accurately determine the gestational age of their pregnancy when they conceive.

Risks and Benefits of OCPs

Risks	Comments
Myocardial Infarction (MI)	Risk increased 20-fold in smokers who use OCPs compared to those who do not use OCPs. Absolute risk of MI in women <35 who are smokers is negligible, and smoking is not a contraindication to OCPs in this group.
Ischemic stroke	Risk increased about 2-fold. 10-fold increase in women with hypertension. Risk decreased if blood pressure was checked and hypertension treated prior to initiation of OCP
Venous thromboembolism (VTE)	Risk of DVT or pulmonary embolism (PE) is increased 4-fold in women of average risk. Risk increases with age and smoking. VTE increased among patients with protein C or S deficiency or Factor V Leiden mutation (30-fold increase in women with Factor V who take OCPs). Absolute risk of death from thromboembolism is 4 per million oral contraceptive users per year.
Hypertension	Relative risk of developing hypertension is 1.8 in current users. Increased risk disappears with discontinuation of OCPs.
Worsening of migraine headaches	The relative risk of stroke is increased 2.8-fold in women with migraine headaches who take OCPs. Giving OCPs to women with focal migraine symptoms is contraindicated.
Non-contraception Benefits	
Decrease in incidence of ovarian cancer	Observational cohort studies have shown a 50% reduction among OCP users.
Reduced incidence of endometrial cancer	Relative risk of endometrial cancer is 0.6 in OCP users.
Reduction in severity of dysfunctional uterine bleeding (DUB)	80% reduction in severity of DUB and quality of life measures compared with 50% in patients taking placebo.
Decrease in iron deficiency anemia due to reduction in menstrual flow	Women on oral contraceptives have higher hemoglobin (3-6 mg/dL higher) and ferritin (2-18 mg/dL) levels compared with controls.
Improvement in acne and hirsutism	Different types of progestin in the various OCP preparations are not important clinically--all OCPs reduce androgen levels and improve acne and hirsutism.
Reduction in dysmenorrhea	OCPs reduce prostaglandin production and uterine contractions at menses resulting in decreased dysmenorrhea.

Risks	Comments
Reduction in functional ovarian cysts	OCPs suppress ovulation, thereby decreasing functional cysts of ovary

Other Hormonal Preparations

Type	Brand Name	Dosage and Route of Administration	Comments
Depo-medroxyprogesterone acetate	Depo-Provera®	150 mg intramuscularly (IM) every 3 months. First injection should be within 5 days of first day of menstrual cycle	Amenorrhea occurs in 50% of patients within a year. May take months for menses to resume after last injection. Side effects include irritability or depression, weight gain, hair loss, acne, irregular bleeding. Useful in women with contraindication to estrogen (migraines, DVT, smokers over age 35). In November, 2004 the U.S. Food and Drug Administration (FDA) issued a warning regarding depo-provera and bone density noting that since depo-provera is associated with significant loss of bone density, it should only be used long-term (>2years) when other methods of contraception are inadequate.
Estrogen-progestin patches	Ortho-Evra®	One patch per week x 3 weeks, then one week off.	Improves compliance. If falls off completely, replace immediately with a new patch. If off >24 hours, use backup method x 7 days. Cost: $42/month. Not covered by most insurers. Less effective in obese women (>198 lbs).
Vaginal ring	NuvaRing®	Use for three weeks, then remove x 1 week.	Continuous absorption rates of estrogen and progestin. Improves compliance. Patients rarely may experience vaginal irritation, discharge. If removed for > 3 hours during the 3 active weeks, patient should use back-up x 7 days. Costs $42/month--not covered by

Type	Brand Name	Dosage and Route of Administration	Comments
			most insurers.
Levonorgestrel IU		Releases 20 micrograms per day levonorgestrel. Inserted by physician, and it is approved to remain in place x 5 years.	Very effective method of contraception. Decreases menstrual blood loss. By 1 year, 20% of users have amenorrhea. Very effective treatment for dysfunctional uterine bleeding. Minimal risk of infection--should only be used in monogamous individuals or patients at low risk of sexually transmitted diseases. Cost: $450/5 years ($7.50/month--less expensive than OCPs).

Barrier Contraception

Barrier methods of contraception involve the use of mechanical devices that prevent the sperm from going into the cervix. The efficacy of all the barrier methods is enhanced with the use of spermicidal jellies. These are available over the counter and are inexpensive.

Type	Highest Failure Rate	Advantages	Disadvantages	Comments
Condom	12%	• Decreases sexually transmitted diseases (STDs)	• Not controlled by the female partner • May come off during intercourse • Often uncomfortable for male partner	Some women have latex allergies and may have to use non-latex condoms.
Diaphragm	18%	• No hormonal side effects	• Requires planning ahead for insertion • Does not prevent STDs • May be associated with urinary	Needs to be fitted by health professional and requires a prescription. A woman should be refitted if more than 10 pound weight gain or loss, and after childbirth. Instruct patients that they may insert up to 2 hours

Type	Highest Failure Rate	Advantages	Disadvantages	Comments
			tract infections • Described as "messy" because of need to use with contraceptive jelly • May be associated with slight increase in toxic shock syndrome	before intercourse, and it should remain in place for 6 hours afterwards. Should be used with about a quarter-sized dollop of spermicidal jelly or cream that should be spread around the inner surface of the diaphragm.
Cervical cap	18%	• Less perceptible to both partners than the diaphragm • Fewer urinary tract infections (UTIs) than with diaphragm • Less "messy"	• About half of women find it difficult to insert and remove. • Not widely available (may be ordered via the web) • Cannot be used in women with abnormalities of the cervix, current vaginitis, ongoing evaluation for abnormal Pap test • Cannot be used during menstruation • May cause cervical abrasion or laceration	Needs to be fitted by health professional and needs to be ordered by health professional. Greater level of patient expertise is required than for the diaphragm. Requires planning ahead for insertion.
Lea contraceptive	9%	• One size fits all--no	• Expensive: $75	Must be left in for 8 hours after

Type	Highest Failure Rate	Advantages	Disadvantages	Comments
barrier		need for fitting • Easy to use - has loop for easier removal, and valve to allow fluids out	• Requires planning ahead for insertion	intercourse. Can be washed and reused for a year. No data on STDs. Ordered online with doctor's prescription.
Spermicidal jelly, film, foam, or suppositories	21%	• No prescription required	• Requires planning ahead for insertion • Does not prevent STDs • Described as "messy" because of need to use with contraceptive jelly	Frequent use of Nonoxyl-9 may increase human immunodeficiency virus (HIV) transmission by causing vaginal irritation.
Female condom (Brand name Reality)	3% 6 month failure rate	• No prescription required • 97% reduction of incidence of infection with HIV • Does not require male partner erection for use • Does not need to be removed immediately after ejaculation	• Expense - costs $3.95/condom • Ring is visible outside of the vagina • Can make noises during intercourse • One time use • Less effective for contraception than other methods (e.g., OCP)	• Brand name "Reality" • Can be ordered through website • Use encouraged by World Health Organization (WHO) • Broader protection than male condom, since base of penis is also covered

Intra-Uterine Devices (IUDs)

IUDs were unpopular about a decade ago. At that time, the use of the Dalkon shield led to increased rates of pelvic inflammatory disease (PID) due to the design of the polyfilament tail. There were also of reports about increased rates of endometritis and lowered fertility after removal. Newer devices have been shown to be associated with fertility rates after removal that are comparable to those in women who have not used IUDs, as long as there is no history of infection in the IUD users. In addition, contrary to popular belief, IUDs are not associated with an increased risk of ectopic pregnancy (because the overall pregnancy rate is lower) or pelvic inflammatory disease.

IUDs are a very effective and reversible method of birth control. It is important to note that they should not be used in women with history of frequent STDs, or women who have multiple sexual partners. They must be inserted by a health professional.

Types of IUDS

Type	Efficacy	Cost	Duration of Use	Advantages	Disadvantages
Copper T IUD (Brand name "Paragard")	98%	$344	May stay in for 10 years	• Useful in women who cannot take estrogen • May be inserted at 6 weeks postpartum, or after a pregnancy termination • May be inserted after an unprotected sexual encounter (up to 5 days after the encounter) to prevent pregnancy--most effective form of emergency contraception	• Increases days of menstrual bleeding • No protection against STDs
Levonorgestrel IUD (Brand name "Mirena")	99.9%	$450	5 years	• Decreases anemia associated with heavy menses • Highly effective (99.9%) • Decreases menorrhagia	• Initially, more days of bleeding for the first few months, but fewer days of bleeding after 6

Type	Efficacy	Cost	Duration of Use	Advantages	Disadvantages
				and associated dysmenorrhea • Reversible • Delivers even less progestin than the mini-pill (progestin only), with minimal systemic side effects • Protective against uterine hyperplasia • May be associated with a reduced risk of endometrial cancer	months • Barrier method needed to protect against STDs • 20% amenorrhea at one year

Surgical Methods for Contraception

Method	Description	Efficacy	Comment
Vasectomy	Ligation of the vas deferens can be performed under local anesthesia.	<1% pregnancy rate over 3 year period after procedure in men with azoospermia post-procedure	Semen analysis should be checked after procedure. Men should be counseled that procedure is permanent. However 50-70% of men who choose reversal of vasectomy recover their fertility.
Tubal ligation	Disruption of patency of Fallopian tubes can be achieved by ligation, segmentectomy, clips, coils, plugs, or electrical current. Procedure can be done laparoscopically or hysteroscopically, and may be done as an outpatient, or shortly after delivery.	1-2% pregnancy rate over 10 year period. Pregnancy rates are higher in younger women (<30 years).	For those who do become pregnant, risk of ectopic pregnancy is higher than in general population (7.3 per 1,000 procedures). Rates of ovarian cancer lower in women who have had tubal ligation.

Emergency Contraception

In the past few years, a number of new methods of contraception have been developed that can be used after an episode of unprotected sex to prevent

fertilization and/or implantation. Although these methods can be used up to 5 days after an episode of unprotected sex, efficacy rates are higher when used as soon as possible after intercourse.

Method	How to Prescribe	Efficacy	Comments
Combined OCPs	Any OCP will work as long as estrogen component adds up to 100 micrograms per dose. Take first dose within 72 hours of intercourse, and second dose 12 hours later. Recently, a formulation has been marketed expressly for this purpose (Preven™), which contains ethinyl estradiol and levonorgestrel. Should be prescribed with an anti-emetic.	75%	The most common side effects are: • Nausea • Vomiting • Menstrual irregularities • Breast tenderness • Headache • Abdominal pain/cramps • Dizziness
Levonorgestrel (LNG) (Plan B®)	Usual practice is to prescribe 0.75 mg within 5 days of intercourse, and again 12 hours later. Can also be given as a single dose (1.5 mg, or two tablets of Plan B) with the same efficacy.	75%	Side effects: • Abdominal pain • Nausea (less than with the combined OCP regimen) • Menstrual irregularities • Has slightly higher efficacy than combined oral contraceptives
Copper T IUD	Should be inserted within 5 days after intercourse	99%	This method should be used when efficacy is the most important factor to the woman and the woman plans to continue IUD use.
Mifepristone	600 mg single dose. Should be given within 72 hours of unprotected intercourse. (This is actually medical abortion dose...not emergency contraception dose.) (For emergency contraception: 10 mg of mifepristone given within 5 days of intercourse, but this dose not available in US).	Similar efficacy to levonorgestrel	

Pregnancy Termination

Primary care providers can play a role in confirming the diagnosis of pregnancy, determining the gestational age, determining whether the pregnancy is desired, and providing options, counseling, and information about the procedure and the expected post-procedure course. They also can play a role in counseling the patient about the emotional aspects of pregnancy termination, providing appropriate contraception to prevent future unwanted pregnancy, and performing the post-procedure check-up.

Cost and Insurance Coverage of Pregnancy Termination

The cost of an abortion is about $400 and is covered by Masshealth and most major insurance carriers. If the patient is a minor and has Masshealth through her parents, Masshealth does not inform the parents of payment for a pregnancy termination. In Massachusetts, patients under 18 years of age require parental consent, unless they obtain consent from a judge. Minors may elect to have a pregnancy termination in a state that does not mandate parental consent (Connecticut, New York, or Vermont).

Evaluation and Management of the Patient who Plans to Undergo Pregnancy Termination

When the unplanned pregnancy is confirmed, the primary care clinician should

- Screen the patient for STDs (when appropriate i.e., age < 25 or new or multiple partners), given that the pregnancy is the result of unprotected intercourse.
- Order a pre-procedure ultrasound to verify gestational age and to rule out ectopic pregnancy.
- Assess the patient's feelings about the pregnancy termination and determine whether the patient needs pre-procedure counseling. Explain to the patient that post-procedure counseling is available.
- Refer the patient to a provider who is trained in performing pregnancy termination.
- Offer a description of the procedure and what the patient may expect (see below).

Surgical Pregnancy Termination Methods

Method	Description	Comments
Suction curettage	First trimester. Performed at 5-13 weeks. Cervical dilatation is performed using rods, then a cannula is inserted into the uterus and uterine contents are aspirated.	• May be performed as soon as intrauterine pregnancy is confirmed--as early as 5 weeks. May be performed up to 13 weeks. • Can be performed under local anesthesia in the outpatient setting. Some outpatient facilities offer conscious sedation or total intravenous anesthesia.

Method	Description	Comments
		• Cervical laceration and uterine perforation are rare complications. • Most common risks are infection, bleeding, or need for repeat procedure for blood clots (1-2%).
Dilation and extraction	Second trimester. On the first day, the cervix is dilated with laminaria. Misoprostol or a second day of laminaria is sometimes necessary for further dilation. Extraction is performed on the second or third day.	• Morbidity is lower with extraction than with induction of labor. • Hemorrhage from uterine perforation, cervical lacerations, uterine atony, or retained products of conception. Mortality rate is 12 per 100,000 procedures over 20 week's gestation (vs. 0.6 per 100,000 procedures in the 1st trimester). Complication rates increase with advancing gestational age and are greatest over 20 weeks gestation.
Induction of labor with misoprostol, prostaglandin gel (e.g., cervidil), or pitocin	Second trimester. Laminaria are placed for cervical dilation/ preparation, then labor is induced with misoprostol.	• Risk of hemorrhage, infection, uterine rupture • Risk of failure requiring dilation and extraction • Risk of retained placenta requiring dilation and curettage

Anesthesia

Local anesthesia with or without conscious sedation is preferred for most first and second trimester procedures. Pre-procedure administration of a nonsteroidal anti-inflammatory drug (NSAID) decreases the cramping that usually occurs after the procedure. General anesthesia is done if the patient desires, or if extensive uterine manipulation is anticipated. Data from the late 1970's showed that general anesthesia was less safe than local. General anesthesia is now much safer, but still may carry additional risk over local and accounts for about a third of the first trimester termination deaths.

Medical Termination of Pregnancy

Mifepristone is an antiprogestin that can be given within the first nine weeks of a pregnancy for the purposes of termination. This agent was approved for use in the U.S. in 2000, after its successful use in Europe for over a decade. When given in combination with misoprostol, a prostaglandin, there is a 92 to 98% rate of complete termination of pregnancy.

Requirements

- Provider should be trained to do medical termination of pregnancy and should be able to provide, or refer patient for, necessary treatment in the event of failure of this method to terminate the pregnancy.
- Access to ultrasonography. Since the agents are only approved for the first 7 weeks of pregnancy, it is critical that the provider have access to ultrasonography to make an accurate assessment of gestational age and to ensure that the pregnancy is not ectopic.
- Access to surgical back-up. The provider should either be able to provide suction curettage or have an agreement with another provider who can, in case of incomplete abortion or serious bleeding.
- Transfusion resources. There should be access to a blood transfusion facility.
- Reliable follow-up. Confirmation of termination of the pregnancy is critical, since some of the medications used in pregnancy termination are associated with teratogenicity. Absolute risk of teratogenicity post-exposure, however, is very low.
- Physicians need to sign an agreement with the manufacturer, and patients must read the manufacturer's medication guide and sign a consent form. Any serious complications or the presence of an ongoing pregnancy after treatment need to be reported to the manufacturer. See the FDA Web site (www.fda.gov/cder/drug/infopage/mifepristone/default.htm) for prescriber and patient information, and the consent forms. Information is also available at the manufacturer's Web site (www.earlyoptionpill.com).

Contraindications

- Allergy to mifepristone or misoprostol
- Pregnancy with IUD in place (IUD should be removed first), or any other potential obstruction to cervical canal (fibroids, cervical stenosis)
- Ectopic pregnancy
- Gestational trophoblastic disease
- Inherited porphyrias
- Steroid use or chronic adrenal insufficiency
- Coagulopathy, or use of anticoagulants
- Inability to sign consent form

Dosages and Protocol

Clinicians prescribing medical abortion should be aware that there are two protocols: one that the FDA has approved and one that is the most commonly used, standard regimen, which is termed the "evidence-based" regimen. There is a large body of evidence to support the "evidence-based" regimen. When prescribing mifepristone for medical abortion, the pharmaceutical company requires that the patient sign a special consent form that comes with the medication describing the FDA-approved regimen. If the clinician is administering the evidence-based regimen, patients should sign an additional consent form that explains why a different protocol is being used.

Please refer to the original guideline document for a table that lists dosages of the two protocols.

Side Effects

- Abdominal pain and cramps are expected. Most women require some form of analgesia during the procedure. NSAIDs are effective and do not change the efficacy of the drugs used. Mild narcotics (acetaminophen with codeine) are also useful.
- Bleeding. Vaginal bleeding that is heavier than a typical period usually occurs with medical abortion, and lasts typically 1 to 2 weeks. Severe bleeding may require curettage or transfusion, but this only occurs in 1 in 500 women.
- Gastrointestinal problems. Nausea, vomiting, and diarrhea occur in about 20% of women as a result of the prostaglandin.

Comparison of Medical and Surgical Pregnancy Termination

	Medical	Surgical
Timing	May be done up to 9 weeks gestation	May be done as soon as intrauterine pregnancy is confirmed--as early as 5 weeks
Anesthesia	None	Required
Side effects	Pain, bleeding expected	Usually few side effects
Efficacy	92-98% effective; failures require surgical intervention	98-99% effective
Privacy	Patient may not need to go to a pregnancy termination center, and the actual termination will likely occur at home.	Procedure needs to take place in a day surgical suite or an office setting.
Patient Satisfaction	Patient choice is the most important factor in satisfaction. There are high rates of satisfaction with both methods. In one randomized controlled trial among patients without a preference who allowed themselves to be randomized to medical vs. surgical method, acceptability of surgery was found to be higher	

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The primary care clinician can play a significant role in the health of women of reproductive age by:

- Educating patients about the need for contraception and pregnancy planning
- Prescribing appropriate contraception
- Ensuring that patients have knowledge of and access to emergency contraception

Refer to the "Major Recommendations" field for advantages and benefits of individual methods of contraception and pregnancy termination.

POTENTIAL HARMS

Refer to the "Major Recommendations" field for risks, side effects, and disadvantages of individual methods of contraception and pregnancy termination.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Who should NOT take oral contraceptive pills (OCPs)?
    - Patients with previous history of venous thromboembolism
    - Patients with known Factor V Leiden mutation (risk of clot increased 30-fold) or other thrombophilia condition (e.g., prothrombin mutation, Protein C or S deficiency)
    - Smokers 35 years of age or older
    - History of breast cancer
    - Uncontrolled hypertension
    - History of stroke
    - History of migraine with neurologic symptoms (there is some controversy to this recommendation. This is a relative contraindication.)
    - Undiagnosed uterine bleeding
    - Liver disease
- Contraindications to the medical termination of pregnancy
    - Allergy to mifepristone or misoprostol
    - Pregnancy with intrauterine device (IUD) in place (IUD should be removed first), or any other potential obstruction to cervical canal (fibroids, cervical stenosis)
    - Ectopic pregnancy
    - Gestational trophoblastic disease
    - Inherited porphyries
    - Steroid use or chronic adrenal insufficiency
    - Coagulopathy, or use of anticoagulants
    - Inability to sign consent form

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guide is not intended to convey rigid standards. Instead, it should be tailored to the needs of the individual patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Brigham and Women's Hospital. Contraception and family planning. A guide to counseling and management. Boston (MA): Brigham and Women's Hospital; 2005. 15 p. [6 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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GUIDELINE DEVELOPER(S)

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GUIDELINE COMMITTEE

Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Brigham and Women's Hospital Web site.

Print copies: Available from the Brigham and Women's Hospital, 75 Francis Street, Boston, Massachusetts 02115. Telephone: (800) BWH-9999.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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